WHITE PAPER NO. 10 – APPLICABILITY OF THE NRC RECOMMENDATIONS FOR PCB-CONTAMINATED SEDIMENT SITES AND EPA'S 11 CONTAMINATED SEDIMENT MANAGEMENT PRINCIPLES

Response to Comments by The Fox River Group

COMMENTS OF THE FOX RIVER GROUP ON THE WISCONSIN DEPARTMENT OF NATURAL RESOURCES' DRAFT REMEDIAL INVESTIGATION, DRAFT FEASIBILITY STUDY DRAFT BASELINE HUMAN HEALTH AND ECOLOGICAL RISK ASSESSMENT AND PROPOSED PLAN

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ABSTRACT

Commenters suggested that the *Proposed Remedial Action Plan, Lower Fox River and Green Bay* (Proposed Plan) (WDNR and EPA, 2001) does not meet the National Contingency Plan (NCP) criteria and was therefore unlawful. Further, commenters concluded that there had been substantial improvements in the ability of removal technologies and targets, but that none of the *ex-situ* options is completely effective in eliminating risk. And, these risks should be considered when comparing *in-situ* versus *ex-situ* management options. This White Paper demonstrates how the Proposed Plan, and supporting documents, meet the requirements of the NCP, as well as the recommendations of the National Research Council (NRC) and the recently released United States Environmental Protection Agency (EPA) Sediment Management Principles.

INTRODUCTION

Based on national and growing concern regarding the long-term management of polychlorinated biphenyl (PCB)-contaminated sediments, the National Academy of Sciences (NAS) was mandated by the United States Congress, via the NRC, to address the complexities and risks associated with managing PCB-contaminated sediments. The NRC was tasked with reviewing the availability, effectiveness, cost, and effects of technologies used for the remediation of sediments containing PCBs. The results of their findings were published in a document titled *A Risk Management Strategy for PCB-contaminated Sediments* (NRC, 2001). Based on their review of PCB effects at several sites nationally, the NRC concluded that PCBs in sediment do pose a chronic risk to human health and the environment, and that these risks must be managed. The NRC developed a list of recommendations that captured a need for remedies to be site-specific and risk-based, and that no one remedy (dredging, capping, or monitored natural recovery) is applicable or preferred for all sites.

The recommendations of the NRC were adapted by the EPA in a document titled, *Principles for Managing Contaminated Sediment Risks at Hazardous Waste Sites* (EPA, 2002). A copy of that document is attached to this White Paper. EPA used the guiding principles defined by the NRC to develop a set of 11 risk management principles for application at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) or Resource Conservation and Recovery Act (RCRA) sediment sites. The EPA guidance principles specify use of scientific, risk-based, site-specific remedy decisions using an iterative decision process, as appropriate, which evaluates the short-term and long-term risks of all potential cleanup alternatives. These principles are also consistent with the nine remedy selection criteria defined in the NCP (40 Code of Federal

Regulations [CFR] Part 300.430). Application of these principles does not affect existing statutory and regulatory requirements.

A comparison of the EPA's 11 management principles and the NRC recommendations are presented below. In general, EPA re-articulated the NRC recommendations, but developed more specificity to site cleanups under CERCLA or RCRA. In addition, EPA added a principle not articulated by the NRC that required the agency to maximize the effectiveness of institutional control.

EPA Risk Management Principles	NRC Recommendations
1. Control sources early.	• Ensure source control.
2. Involve the community early and often.	• Involve community and trustees early.
3. Coordinate with state, local, tribal, and natural resource trustees.	• Societal, cultural, and economic impacts should also be considered.
4. Develop and refine a conceptual site model that considers sediment stability.	• Additional research is needed to assess chemical mixtures and fate/transport processes.
5. Use an iterative approach in a risk-based framework.	• Use a risk-based framework.
6. Evaluate the assumptions and uncertainties associated with site models.	• Select site-specific management decisions.
7. Select site-specific approaches that will achieve risk-based goals.	• PCB exposure may result in adverse human and ecological effects.
8. Ensure that sediment cleanup levels are clearly tied to management goals.	• There is no presumptive remedy. • Management options can reduce but not eliminate PCB exposure.
9. Maximize the effectiveness of institutional controls.	
10. Design remedies to minimize short-term risks while achieving long-term goals.	• Key consideration is management of risks; remedial technology is secondary.
11. Monitor to assess effectiveness.	• Long-term monitoring should be conducted to assess effectiveness.

The *Remedial Investigation for the Lower Fox River and Green Bay, Wisconsin* (RI) (RETEC, 2002a) and *Feasibility Study for the Lower Fox River and Green Bay, Wisconsin* (FS) (RETEC, 2002b) are consistent with the findings of the NAS's NRC report entitled *A Risk-Management Strategy for PCB-Contaminated Sediments* (NRC, 2001). The remedy alternatives and action levels developed for the Lower Fox River and Green Bay also considered the 11 guiding principles defined by the EPA. Each of the 11 EPA principles and how they were applied to the Lower Fox River and Green Bay RI/FS process are briefly described below.

1. CONTROL SOURCES EARLY

Historically, PCBs were discharged into the Lower Fox River with wastewaters generated from the use and manufacture of carbonless copy paper. Under the Toxic Substances Control Act (TSCA), all manufacture and use of PCBs was banned. Through the efforts of the Wisconsin Department of Natural Resources' (WDNR's) Wisconsin Pollution

Discharge Elimination System (WPDES) program and the discontinued use of PCBs in the production of carbonless copy paper, point source introduction of PCBs into the Lower Fox River has essentially been eliminated.

Surface water quality of the Lower Fox River and Green Bay has been extensively monitored over the last 40 years to determine direct and indirect sources of PCBs to the sediments under investigation. Potential transport pathways such as: outfall discharges, air deposition, groundwater migration, adjacent landfills, sediment resuspension and settling, and urban and agricultural runoff, have been monitored and quantified during previous investigations. These investigations have concluded that today, river sediments are the only significant source of PCBs within the Lower Fox River system. These same investigations and data also have formed the base of knowledge for the PCB fate and transport models constructed and used for this site.

2. INVOLVE THE COMMUNITY EARLY AND OFTEN

Meaningful community involvement is a critical component of the site characterization, risk assessment, remedy evaluation, and remedy implementation processes. The PCB contamination of the Lower Fox River has been at the forefront of public discussion and debate for over 20 years. The forum for this discussion has continually evolved. In the early 1980s, following the identification of the Lower Fox River and southern Green Bay as an Area of Concern (AOC) by the International Joint Commission (IJC), a Remedial Action Plan (RAP) public advisory committee was established. Numerous RAP committees were established to address various problems facing the Lower Fox River and Green Bay ecosystems. One such committee, the Science and Technical Advisory Committee (STAC) still meets today and offers input into resolution of the PCB issues. Following from the RAP, the Fox River Coalition (FRC) formed to specifically address the PCB-contaminated sediment issue. The FRC was an assemblage of area municipal, county, state, and local industry leaders that set out to develop a river-wide cleanup plan. The FRC held numerous public meetings and performed some of the initial research into remedial options.

As discussed in the FS (Section 9; RETEC, 2002b), WDNR and EPA have held numerous public/community town meetings, solicited input (door-to-door) from residents, and encouraged active participation during the demonstration sediment remediation projects conducted at Deposit N and Sediment Management Unit (SMU) 56/57 in the Lower Fox River. To further public participation, EPA has twice provided substantial grants to the Clean Water Action Coalition. WDNR regularly publishes the *Fox River Current* newsletter, which is distributed to over 10,000 parties.

To provide greater public input into the development of the final RI/FS and *Baseline Human Health and Ecological Risk Assessment for the Lower Fox River and Green Bay, Wisconsin, Remedial Investigation and Feasibility Study* (BLRA) (RETEC, 2002c), the agencies released a draft of these documents for public review and comment in February 1999. These draft documents were also subjected to peer reviews conducted by both

EPA and the potentially responsible parties, the Fox River Group. Based on all the public and peer review comments as well as comments received from the National Remedy Review Board, WDNR modified the RI/FS and BLRA and released another draft in October 2001, for additional public comment, along with the Proposed Plan. Most recently, the agencies have reviewed over 4,800 public comments collected during the latest public comment period. The Final RI/FS and BLRA were issued based upon the comments received, as is the Record of Decision.

WDNR also maintains a public website for easy access to data, public documents, meeting minutes, and project updates and resolutions. WDNR is committed to serving the interests of local communities, and facilitating their informed participation, in a balanced and effective manner.

3. COORDINATE WITH STATES, LOCAL GOVERNMENTS, TRIBES, AND NATURAL RESOURCE AGENCIES

At the very start of the RI/FS and BLRA process in 1997, WDNR, EPA, United States Fish and Wildlife Service (USFWS), National Oceanic and Atmospheric Administration (NOAA), and the Oneida and Menominee Indian tribes signed a Memorandum of Understanding (MOU). The MOU resulted in the formation of an Intergovernmental Partnership (IGP). Under this IGP, the state as the natural resource trustee coordinates early and often with local governments, tribes, and other Natural Resource Trustees to ensure that all relevant information and viewpoints are being considered when making remedial decisions. In addition, early in the RI/FS and BLRA process, a Biological Technical Assistance Group (BTAG) was formed to assure that the relevant issues and concerns of each regulatory agency and Natural Resource Trustee were addressed in the RI/FS and BLRA process.

4. DEVELOP AND REFINE A CONCEPTUAL SITE MODEL THAT CONSIDERS SEDIMENT STABILITY

The NRC recommends that when models are used to describe relevant PCB exposure pathways that: (1) uncertainty in these models is described, (2) models are calibrated, and (3) models are peer reviewed. The NRC also recommends that the conceptual model includes significant point and non-point sources, release mechanisms, and transport pathways; these pathways are discussed in the RI (RETEC, 2002a).

A comprehensive set of fate and transport models were developed in collaboration with WDNR, EPA, the Fox River Group, which have undergone internal and peer review. These models include the Whole Lower Fox River Model (wLFRM), the Fox River Food Model (FRFood), Green Bay Toxics Model Version E (GBTOXe), and the Green Bay Food Model (GBFood) and have the Lower Fox River and Green Bay fate/transport models are mathematical representations of river hydrodynamics and biota exposure and effect scenarios. These are the models specifically calibrated for the RI/FS and are documented in the *Model Documentation Report for the Lower Fox River and Green Bay, Wisconsin* (MDR) (WDNR and RETEC, 2002). A discussion of the specific

models, development history and parameterization is found in Appendix B of the MDR. These models complied with EPA principles by calibrating these models with site-specific data and defining the uncertainty associated with the model assumptions.

Sediment stability was evaluated in the hydrodynamic models via river flooding, scour events, and bed load properties, and calibrated with bathymetric measurements over time. The issue of sediment resuspension is discussed in detail within the MDR for both wLFRM and GBTOXe. Although these models were designed early in the process to guide site investigations and facilitate communication among stakeholders, they have been updated periodically to incorporate new site-specific information. The MDR discusses the PCB fate, transport, and food web models used for the Lower Fox River and Green Bay along with their assumptions, calibrations, and uncertainty.

5. USE AN ITERATIVE APPROACH IN A RISK-BASED FRAMEWORK

The risk assessment process implemented for the Lower Fox River and Green Bay followed NRC and EPA recommendations by using a flexible, iterative, and tiered approach, which involved risk characterization that began with a *Screening Level Human Health and Ecological Risk Assessment: Lower Fox River Site, Wisconsin* (SLRA), followed by the BLRA that incorporated a re-evaluation of potential impacts and other site assumptions (RETEC, 1998, 2002c). The BLRA also conformed with NRC recommendations by assuring that: (1) "site-specific" data were evaluated, (2) all available scientific information was incorporated into the assessment, and (3) all affected parties (community, site owners, regulatory agencies) were involved in the review process through the RAP, RAPSTAC, and Fox River Coalition groups. The SLRA was released in 1998 and underwent a public review process by interest groups, local regulators, tribes, and Natural Resource Trustees. The BLRA, released in 2001, was peer reviewed by the AEHS. Comments and concerns were incorporated into the document through several rounds of public involvement, review, and iterations.

6. CAREFULLY EVALUATE THE ASSUMPTIONS AND UNCERTAINTIES ASSOCIATED WITH SITE CHARACTERIZATION DATA AND SITE MODELS

The EPA recommends that, during development of site conceptual models and the characterization of site risks, all assumptions and uncertainties be carefully described and evaluated. As a part of the overall program, WDNR and EPA had constructed the Fox River Database (FRDB). The FRDB is a comprehensive collection of all available data sets produced for the river and bay. Over 500,000 data points were included in the FRDB only if they met the strict quality assurance and quality control criteria required under the NCP. The collection and evaluation of these data are documented in the *Data Management Summary Report*, an appendix to the RI. As part of the overall process, EPA had an independent peer review evaluate the FRDB. The BLRA discussed uncertainty associated with the supporting site data, temporal and spatial variability, and toxicity and exposure assumptions made during development of the site models. The

uncertainties and assumptions are discussed in the BLRA (RETEC, 2002c) and the MDR (WDNR and RETEC, 2002).

7. SELECT SITE-SPECIFIC, PROJECT-SPECIFIC, AND SEDIMENT-SPECIFIC RISK MANAGEMENT APPROACHES THAT WILL ACHIEVE RISK-BASED GOALS

By WDNR and EPA following strictly the CERCLA process supports the NRC's statement that "there is no presumption of a preferred or default risk-management option that is applicable to all PCB-contaminated-sediments sites" (EPA, 2002). The FS does not select a preferred remedy, instead a range of alternatives, action levels, costs, and their relative risk reduction are presented. Alternatives are compared to each other relative to CERCLA criteria and site-specific Remedial Action Objectives (RAOs). Remedies that potentially reduce the identified site-specific risks and meet the RAOs are evaluated and compared to a natural attenuation (no action) option to identify the most effective management strategy, or combination of strategies for the site.

Final selection of a remedy (and action level) will be a joint WDNR and EPA management decision that will be made in consultation with the IGP. The remedy decision process for the Lower Fox River/Green Bay will involve the evaluation of site-specific data and other project-specific considerations to characterize site risk, community concerns, and long-term benefits. The final remedy for this site will consider the most effective method for reducing PCB exposure and the ensuing effects of such exposure.

8. ENSURE THAT SEDIMENT CLEANUP LEVELS ARE CLEARLY TIED TO RISK MANAGEMENT GOALS

Although sediment threshold values have been developed and used for identifying areas to be remediated, EPA recommends that other measures be used to ensure that risk reduction goals are met (e.g., reduction in fish tissue concentrations). For the Fox River, elevated concentrations of chemicals of concern (COCs) have been linked to elevated fish tissue levels, fish consumption advisories, bird mortality, and wildlife reproductive health. The weight of evidence clearly demonstrates that the sediment remains the source of these COCs to the river. Therefore, remedial action levels have been proposed based on residual surface-weighted average sediment concentrations (SWAC) that are protective of human and ecological sediment quality thresholds (SQTs). To ensure that the selected remedy for the Lower Fox River is protective of human health (primarily via fish consumption) and the environment, a Model Long-Term Monitoring Plan (RETEC and SAIC, 2002; Appendix C of the FS) is proposed. Measurement endpoints may include: surface sediment concentrations, benthic invertebrate indices, fish tissue concentrations, bird tissue concentrations, and estimates of bird reproduction. Endpoints will be compared to residual risk levels over time and achievement of the project RAOs.

9. MAXIMIZE THE EFFECTIVENESS OF INSTITUTIONAL CONTROLS AND RECOGNIZE THEIR LIMITATIONS

Due to elevated PCB levels at the Lower Fox River/Green Bay, WDNR issued consumption advisories for fish and waterfowl in 1976 and 1987, respectively, and Michigan issued fish consumption advisories for Green Bay in 1977. These advisories, which remain in place today for particular species, are intended to limit human exposures until the RAOs are met after implementation and completion of a final remedy.

10. DESIGN REMEDIES TO MINIMIZE SHORT-TERM RISKS WHILE ACHIEVING LONG-TERM PROTECTION

In evaluating potential remedies for the Lower Fox River/Green Bay, short-term risks will be minimized to the extent practicable. Risks, such as from resuspended sediment during dredging, will be addressed with the use of appropriate technologies and available control measures. Mitigation methods such as operating hours, routes, and fencing will also be employed to address local short-term implementation issues such as traffic, noise, or recreational use. Admittedly, there will be some instances where short-term risks may inevitably temporarily increase to achieve the long-term remediation goal.

11. MONITOR DURING AND AFTER SEDIMENT REMEDIATION TO ASSESS AND DOCUMENT REMEDY EFFECTIVENESS

A long-term monitoring plan has been prepared as part of the FS to ensure that the selected remedy is adequately mitigating risk and achieving project RAOs. Baseline data, collected before remedial activities begin, will be compared to post-remedy monitoring data. If necessary, the remedy process may be subject to modification to meet the RAOs.

REFERENCES

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
Feb. 12, 2002

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

OSWER Directive 9285.6-08

MEMORANDUM

SUBJECT: Principles for Managing Contaminated Sediment Risks at Hazardous Waste Sites

FROM: Marianne Lamont Horinko */s/ Marianne Lamont Horinko*
Assistant Administrator

TO: Superfund National Policy Managers, Regions 1 - 10
RCRA Senior Policy Advisors, Regions 1 - 10

I. PURPOSE

This guidance will help EPA site managers make scientifically sound and nationally consistent risk management decisions at contaminated sediment sites. It presents 11 risk management principles that Remedial Project Managers (RPMs), On-Scene Coordinators (OSCs), and RCRA Corrective Action project managers should carefully consider when planning and conducting site investigations, involving the affected parties, and selecting and implementing a response.

This guidance recommends that EPA site managers make risk-based site decisions using an iterative decision process, as appropriate, that evaluates the short-term and long-term risks of all potential cleanup alternatives consistent with the National Oil and Hazardous Substances Pollution Contingency Plan's (NCP's) nine remedy selection criteria (40 CFR Part 300.430). EPA site managers are also encouraged to consider the societal and cultural impacts of existing sediment contamination and of potential remedies through meaningful involvement of affected stakeholders.

This guidance also responds in part to the recommendations contained in the National Research Council (NRC) report discussed below.

II. Background

on march 26, 2001, the nrc published a report entitled *a risk management strategy for pcb-contaminated sediments*. Although the nrc report focuses primarily on assessment and remediation of PCB-contaminated sediments, much of the information in that report is applicable to other contaminants. Site managers are encouraged to read the NRC report, which may be found at http://www.nrc.edu.

In addition to developing these principles, OSWER, in coordination with other EPA offices (Office of Research and Development, Office of Water, and others) and other federal agencies (Department of Defense/U.S. Army Corps of Engineers, Department of Commerce/National Oceanic and Atmospheric Administration, Department of the Interior/U.S. Fish and Wildlife Service, and others) is developing a separate guidance, *Contaminated Sediment Remediation Guidance for Hazardous Waste Sites* (Sediment Guidance). The Sediment Guidance will provide more detailed technical guidance on the process that Superfund and RCRA project managers should use to evaluate cleanup alternatives at contaminated sediment sites.

While this directive applies to all contaminants at sediment sites addressed under CERCLA or RCRA, its implementation at particular sites should be tailored to the size and complexity of the site, to the magnitude of site risks, and to the type of action contemplated. These principles can be applied within the framework of EPA's existing statutory and regulatory requirements.

III. RISK MANAGEMENT PRINCIPLES

1. Control Sources Early.

As early in the process as possible, site managers should try to identify all direct and indirect continuing sources of significant contamination to the sediments under investigation. These sources might include discharges from industries or sewage treatment plants, spills, precipitation runoff, erosion of contaminated soil from stream banks or adjacent land, contaminated groundwater and non-aqueous phase liquid contributions, discharges from storm water and combined sewer outfalls, upstream contributions, and air deposition.

Next, site managers should assess which continuing sources can be controlled and by what mechanisms. It may be helpful to prioritize sources according to their relative contributions to site risks. In the identification and assessment process, site managers should solicit assistance from those with relevant information, including regional Water, Air, and PCB Programs (where applicable); state agencies (especially those responsible for setting Total Maximum Daily Loads (TMDLs) and those that issue National Pollutant Discharge Elimination System (NPDES) permits); and all Natural Resource Trustees. Local agencies and stakeholders may also be of assistance in assessing which sources can be controlled.

Site managers should evaluate the potential for future recontamination of sediments when selecting a response action. If a site includes a source that could result in significant recontamination, source control measures will likely be necessary as part of that response action. However, where EPA believes that the source can be controlled, or where sediment remediation will have benefits to human health and/or the environment after considering the risks caused by the ongoing source, it may be appropriate for the Agency to select a response action for the sediments prior to completing all source control actions. This is consistent with principle #5 below, which indicates that it may be necessary to take phased or interim actions (e.g., removal of a hot spot that is highly susceptible to downstream movement or dispersion of contaminants) to prevent or address environmental impacts or to control human exposures, even if source control actions have not been undertaken or completed.

2. Involve the Community Early and Often.

Contaminated sediment sites often involve difficult technical and social issues. As such, it is especially important that a project manager ensure early and meaningful community involvement by providing community members with the technical information needed for their informed participation. Meaningful community involvement is a critical component of the site characterization, risk assessment, remedy evaluation, remedy selection, and remedy implementation processes. Community involvement enables EPA to obtain site information that may be important in identifying potential human and ecological exposures, as well as in understanding the societal and cultural impacts of the contamination and of the potential response options. The NRC report (p. 249) "recommends that increased efforts be made to provide the affected parties with the same information that is to be used by the decision-makers and to include, to the extent possible, all affected parties in the entire decision-making process at a contaminated site. In addition, such information should be made available in such a manner that allows adequate time for evaluation and comment on the information by all parties." Through Technical Assistance Grants and other mechanisms, project managers can provide the community with the tools and information necessary for meaningful participation, ensuring their early and continued involvement in the cleanup process.

Although the Agency has the responsibility to make the final cleanup decision at CERCLA and RCRA sites, early and frequent community involvement facilitates acceptance of Agency decisions, even at sites where there may be disagreement among members of the community on the most appropriate remedy.

Site managers and community involvement coordinators should take into consideration the following six practices, which were recently presented in OSWER Directive 9230.0-99 *Early and Meaningful Community Involvement* (October 12, 2001). This directive also includes a list of other useful resources and is available at http://www.epa.gov/superfund/pubs.htm.

(1) Energize the community involvement plan.
(2) Provide early, proactive community support.
(3) Get the community more involved in the risk assessment.

(4) Seek early community input on the scope of the remedial investigation/feasibility study (RI/FS).
(5) Encourage community involvement in identification of future land use.
(6) Do more to involve communities during removals.

3. Coordinate with States, Local Governments, Tribes, and Natural Resource Trustees.

Site managers should communicate and coordinate early with states, local governments, tribes, and all Natural Resource Trustees. By doing so, they will help ensure that the most relevant information is considered in designing site studies, and that state, local, tribal, and trustee viewpoints are considered in the remedy selection process. For sites that include waterbodies where TMDLs are being or have been developed, it is especially important to coordinate site investigations and monitoring or modeling studies with the state and with EPA's water program. In addition, sharing information early with all interested parties often leads to quicker and more efficient protection of human health and the environment through a coordinated cleanup approach.

Superfund's statutory mandate is to ensure that response actions will be protective of human health and the environment. EPA recognizes, however, that in addition to EPA's response action(s), restoration activities by the Natural Resource Trustees may be needed. It is important that Superfund site managers and the Trustees coordinate both the EPA investigations of risk and the Trustee investigations of resource injuries in order to most efficiently use federal and state resources and to avoid duplicative efforts.

Additional information on coordinating with Trustees may be found in OSWER Directive 9200.4-22A *CERCLA Coordination with Natural Resource Trustee*s (July 1997), in the 1992 ECO Update *The Role of Natural Resource Trustees in the Superfund Process* http://www.epa.gov/superfund/programs/risk/tooleco.htm), and in the 1999 OSWER Directive 9285.7-28 P *Ecological Risk Assessment and Risk Management Principles for Superfund Sites* (also available at the above web site). Additional information on coordinating with states and tribes can be found in OSWER Directive 9375.3-03P *The Plan to Enhance the Role of States and Tribes in the Superfund Program* (http://www.epa.gov/superfund/states/strole/index.htm).

4. Develop and Refine a Conceptual Site Model that Considers Sediment Stability.

A conceptual site model should identify all known and suspected sources of contamination, the types of contaminants and affected media, existing and potential exposure pathways, and the known or potential human and ecological receptors that may be threatened. This information is frequently summarized in pictorial or graphical form, backed up by site-specific data. The conceptual site model should be prepared early and used to guide site investigations and decision-making. However, it should be updated periodically whenever new information becomes available, and EPA's understanding of the site problems increases. In addition, it frequently can serve as the centerpiece for communication among all stakeholders.

A conceptual site model is especially important at sediment sites because the interrelationship of soil, surface and groundwater, sediment, and ecological and human receptors is often complex. In addition, sediments may be subject to erosion or transport by natural or man-made disturbances such as floods or engineering changes in a waterway. Because sediments may experience temporal, physical, and chemical changes, it is especially important to understand what contaminants are currently available to humans and wildlife, and whether this is likely to change in the future under various scenarios. The risk assessor and project manager, as well as other members of the site team, should communicate early and often to ensure that they share a common understanding of the site and the basis for the present and future risks. The May 1998 EPA *Guidelines for Ecological Risk Assessment* (Federal Register 63(93) 26846-26924, http://www.epa.gov/superfund/programs/risk/tooleco.htm), the 1997 Superfund Guidance *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (EPA 540-R-97-006, also available at the above web site), and the 1989 *Risk Assessment Guidance for Superfund (RAGS), Volume 1, Part A* (EPA 540-1-89-002, http://www.epa.gov/superfund/programs/risk/ragsa) provide guidance on developing conceptual site models.

5. Use an Iterative Approach in a Risk-Based Framework.

The NRC report (p. 52) recommends the use of a risk-based framework based on the one developed by the Presidential/Congressional Commission on Risk Assessment and Risk Management (PCCRARM, 1997, *Framework for Environmental Health Risk Management*, Vol. 1, as cited by NRC 2001). However, as recognized by the NRC (p. 60): "The framework is intended to supplement, not supplant, the CERCLA remedial process mandated by law for Superfund sites."

Although there is no universally accepted, well-defined risk-based framework or strategy for remedy evaluation at sediment sites, there is wide-spread agreement that risk assessment should play a critical role in evaluating options for sediment remediation. The Superfund program uses a flexible, risk-based framework as part of the CERCLA and NCP process to adequately characterize ecological and human health site risks. The guidances used by the RCRA Corrective Action program (http://www.epa.gov/correctiveaction/resource/guidance) also recommend a flexible risk-based approach to selecting response actions appropriate for the site.

EPA encourages the use of an iterative approach, especially at complex contaminated sediment sites. As used here, an iterative approach is defined broadly to include approaches which incorporate testing of hypotheses and conclusions and foster re-evaluation of site assumptions as new information is gathered. For example, an iterative approach might include pilot testing to determine the effectiveness of various remedial technologies at a site. As noted in the NRC report (p. 66): "Each iteration might provide additional certainty and information to support further risk-management decisions, or it might require a course correction."

An iterative approach may also incorporate the use of phased, early, or interim actions. At complex sediment sites, site managers should consider the benefits of phasing the remediation. At some sites, an early action may be needed to quickly reduce risks or to control the ongoing spread of contamination. In some cases, it may be appropriate to take an interim action to control a source, or remove or cap a hot spot, followed by a period of monitoring in order to evaluate the effectiveness of these interim actions before addressing less contaminated areas.

The NRC report makes an important point when it notes (p. 256): "The committee cautions that the use of the framework or other risk-management approach should not be used to delay a decision at a site if sufficient information is available to make an informed decision. Particularly in situations in which there are immediate risks to human health or the ecosystem, waiting until more information is gathered might result in more harm than making a preliminary decision in the absence of a complete set of information. The committee emphasizes that a 'wait-and-see' or 'do-nothing' approach might result in additional or different risks at a site."

6. Carefully Evaluate the Assumptions and Uncertainties Associated with Site Characterization Data and Site Models.

The uncertainties and limitations of site characterization data, and qualitative or quantitative models (e.g., hydrodynamic, sediment stability, contaminant fate and transport, or food-chain models) used to extrapolate site data to future conditions should be carefully evaluated and described. Due to the complex nature of many large sediment sites, a quantitative model is often used to help estimate and understand the current and future risks at the site and to predict the efficacy of various remedial alternatives. The amount of site-specific data required and the complexity of models used to support site decisions should depend on the complexity of the site and the significance of the decision (e.g., level of risk, response cost, community interest). All new models and the calibration of models at large or complex sites should be peer-reviewed consistent with the Agency's peer review process as described in its Peer Review Handbook (EPA 100-B-00-001, http://www.epa.gov/ORD/spc/2peerrev.htm).

Site managers should clearly describe the basis for all models used and their uncertainties when using the predicted results to make a site decision. As recognized by the NRC report (p. 65), however, "Management decisions must be made, even when information is imperfect. There are uncertainties associated with every decision that need to be weighed, evaluated, and communicated to affected parties. Imperfect knowledge must not become an excuse for not making a decision."

7. Select Site-specific, Project-specific, and Sediment-specific Risk Management Approaches that will Achieve Risk-based Goals.

EPA's policy has been and continues to be that there is no presumptive remedy for any contaminated sediment site, regardless of the contaminant or level of risk. This is consistent with the NRC report's statement (p. 243) that "There is no presumption of a preferred or default risk-management option that is applicable to all PCB-contaminated-sediment sites." At Superfund sites, for example, the most appropriate remedy should be chosen after considering site-specific data and the NCP's nine remedy selection criteria. All remedies that may potentially meet the removal or remedial action objectives (e.g., dredging or excavation, in-situ capping, in-situ treatment, monitored natural recovery) should be evaluated prior to selecting the remedy. This evaluation should be conducted on a comparable basis, considering all components of the remedies, the temporal and spatial aspects of the sites, and the overall risk reduction potentially achieved under each option.

At many sites, a combination of options will be the most effective way to manage the risk. For example, at some sites, the most appropriate remedy may be to dredge high concentrations of persistent and bioaccumulative contaminants such as PCBs or DDT, to cap areas where dredging is not practicable or cost-effective, and then to allow natural recovery processes to achieve further recovery in net depositional areas that are less contaminated.

8. Ensure that Sediment Cleanup Levels are Clearly Tied to Risk Management Goals.

Sediment cleanup levels have often been used as surrogates for actual remediation goals (e.g., fish tissue concentrations or other measurable indicators of exposure relating to levels of acceptable risk). While it is generally more practical to use measures such as contaminant concentrations in sediment to identify areas to be remediated, other measures should be used to ensure that human health and/or ecological risk reduction goals are being met. Such measures may include direct measurements of indigenous fish tissue concentrations, estimates of wildlife reproduction, benthic macroinvertebrate indices, or other "effects endpoints" as identified in the baseline risk assessment.

As noted in the NRC report (p. 123), "The use of measured concentrations of PCBs in fish is suggested as the most relevant means of measuring exposures of receptors to PCBs in contaminated sediments." For other contaminants, other measures may be more appropriate. For many sites, achieving remediation goals, especially for bioaccumulative contaminants in biota, may take many years. Site monitoring data and new scientific information should be considered in future reviews of the site (e.g., the Superfund five-year review) to ensure that the remedy remains protective of human health and the environment.

9. Maximize the Effectiveness of Institutional Controls and Recognize their Limitations.

Institutional controls, such as fish consumption advisories and waterway use restrictions, are often used as a component of remedial decisions at sediment sites to limit human exposures and to prevent further spreading of contamination until remedial action objectives are met. While these controls can be an important component of a sediment remedy, site managers should recognize that they may not be very effective in eliminating or significantly reducing all exposures. If fish consumption advisories are relied upon to limit human exposures, it is very important to have public education programs in place. For other types of institutional controls, other types of compliance assistance programs may also be needed (e.g., state/local government coordination). Site managers should also recognize that institutional controls seldom limit ecological exposures. If monitoring data or other site information indicates that institutional controls are not effective, additional actions may be necessary.

10. Design Remedies to Minimize Short-term Risks while Achieving Long-term Protection.

The NRC report notes (p. 53) that: "Any decision regarding the specific choice of a risk management strategy for a contaminated sediment site must be based on careful consideration of the advantages and disadvantages of available options and a balancing of the various risks, costs, and benefits associated with each option." Sediment cleanups should be designed to minimize short-term impacts to the extent practicable, even though some increases in short-term risk may be necessary in order to achieve a long-lasting solution that is protective. For example, the long-term benefits of removing or capping sediments containing persistent and bioaccumulative contaminants often outweigh the additional short-term impacts on the already-affected biota.

In addition to considering the impacts of each alternative on human health and ecological risks, the short-term and long-term impacts of each alternative on societal and cultural practices should be identified and considered, as appropriate. For example, these impacts might include effects on recreational uses of the waterbody, road traffic, noise and air pollution, commercial fishing, or disruption of way of life for tribes. At some sites, a comparative analysis of impacts such as these may be useful in order to fully assess and balance the tradeoffs associated with each alternative.

11. Monitor During and After Sediment Remediation to Assess and Document Remedy Effectiveness.

A physical, chemical, and/or biological monitoring program should be established for sediment sites in order to determine if short-term and long-term health and ecological risks are being adequately mitigated at the site and to evaluate how well all remedial action objectives are being met. Monitoring should normally be conducted during remedy implementation and as long as necessary thereafter to ensure that all sediment risks have been adequately managed.

Baseline data needed for interpretation of the monitoring data should be collected during the remedial investigation.

Depending on the risk management approach selected, monitoring should be conducted during implementation in order to determine whether the action meets design requirements and sediment cleanup levels, and to assess the nature and extent of any short-term impacts of remedy implementation. This information can also be used to modify construction activities to assure that remediation is proceeding in a safe and effective manner. Long-term monitoring of indicators such as contaminant concentration reductions in fish tissue should be designed to determine the success of a remedy in meeting broader remedial action objectives. Monitoring is generally needed to verify the continued long-term effectiveness of any remedy in protecting human health and the environment and, at some sites, to verify the continuing performance and structural integrity of barriers to contaminant transport.

IV. IMPLEMENTATION

EPA RPMs, OSCs, and RCRA Corrective Action project managers should immediately begin to use this guidance at all sites where the risks from contaminated sediment are being investigated. EPA expects that Federal facility responses conducted under CERCLA or RCRA will also be consistent with this directive. This consultation process does not apply to Time-Critical or emergency removal actions or to sites with only sediment-like materials in wastewater lagoons, tanks, storage or containment facilities, or drainage ditches.

Consultation Process for CERCLA Sites

To help ensure that Regional site managers appropriately consider these principles *before* site-specific risk management decisions are made, this directive establishes a two-tiered consultation procedure that will apply to most contaminated sediment sites. The consultation process applies to all proposed or listed NPL sites where EPA will sign or concur on the ROD, all Non-Time-Critical removal actions where EPA will sign or concur on the Action Memorandum, and all "NPL-equivalent" sites where there is or will be an EPA-enforceable agreement in place.

Tier 1 Process

Where the sediment action(s) for the entire site will address more than 10,000 cubic yards or five acres of contaminated sediment, Superfund RPMs and OSCs should consult with their appropriate Office of Emergency and Remedial Response (OERR) Regional Coordinator at least 30 days before issuing for public comment a Proposed Plan for a remedial action or an Engineering Evaluation/Cost Analysis (EE/CA) for a Non-Time-Critical removal action.

This consultation entails the submission of the draft proposed plan or draft EE/CA, a written discussion of how the above 11 principles were considered, and basic site information

that will assist OERR in tracking significant sediment sites. If the project manager has not received a response from OERR within two weeks, he or she may assume no further information is needed at this time. EPA believes that this process will help promote nationally consistent approaches to evaluate, select and implement protective, scientifically sound, and cost-effective remedies.

Tier 2 Process

This directive also establishes a new technical advisory group (Contaminated Sediments Technical Advisory Group–CSTAG) that will monitor the progress of and provide advice regarding a small number of large, complex, or controversial contaminated sediment Superfund sites. The group will be comprised of ten Regional staff and approximately five staff from OSWER, OW, and ORD. For most sites, the group will meet with the site manager and the site team several times throughout the site investigation, response selection, and action implementation processes. For new NPL sites, the group will normally meet within one year after proposed listing. It is anticipated that for most sites, the group will meet annually until the ROD is signed and thereafter as needed until all remedial action objectives have been met. The specific areas of assistance or specific documents to be reviewed will be decided by the group on a case-by-case basis in consultation with the site team. For selected sites with an on-going RI/FS or EE/CA, the group will be briefed by the site manager some time in 2002 or 2003. Reviews at sites with remedies also subject to National Remedy Review Board (NRRB) review will be coordinated with the NRRB in order to eliminate the need for a separate sediment group review at this stage in the process.

Consultation Process for RCRA Corrective Action Facilities

Generally, for EPA-lead RCRA Corrective Action facilities where a sediment response action is planned, a two-tiered consultation process will also be used. Where the sediment action(s) for the entire site will address more than 10,000 cubic yards or five acres of contaminated sediment, project managers should consult with the Office of Solid Waste's Corrective Action Branch at least 30 days before issuing a proposed action for public comment. This consultation entails the submission of a written discussion of how the above 11 principles were considered, and basic site information that will assist OSW in tracking significant sediment sites.

If the project manager has not received a response from OSW within two weeks, he or she may assume no further information is needed. States are also encouraged to follow these procedures. For particularly large, complex, or controversial sites, OSW will likely call on the technical advisory group discussed above.

EPA also recommends that both state and EPA project managers working on sediment contamination associated with Corrective Action facilities consult with their colleagues in both RCRA and Superfund to promote consistent and effective cleanups. EPA believes this

consultation would be particularly important for the larger-scale sediment cleanups mentioned above.

EPA may update this guidance as more information becomes available on topics such as: the effectiveness of various sediment response alternatives, new methods to evaluate risks, or new methods for characterizing sediment contamination. For additional information on this guidance, please contact the OERR Sediments Team Leader (Stephen Ells at 703 603-8822) or the OSW Corrective Action Programs Branch Chief (Tricia Buzzell at 703 308-8632).

NOTICE: This document provides guidance to EPA Regions concerning how the Agency intends to exercise its discretion in implementing one aspect of the CERCLA and RCRA remedy selection process. This guidance is designed to implement national policy on these issues. Some of the statutory provisions described in this document contain legally binding requirements. However, this document does not substitute for those provisions or regulations, nor is it a regulation itself. Thus it cannot impose legally binding requirements on EPA, states, or the regulated community, and may not apply to a particular situation based upon the circumstances. Any decisions regarding a particular situation will be made based on the statutes and regulations, and EPA decision-makers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. Interested parties are free to raise questions and objections about the substance of this guidance and the appropriateness of the application of this guidance to a particular situation, and the Agency welcomes public input on this document at any time. EPA may change this guidance in the future.

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